

Applicants: Han Htun and Gordon L. Hager
U.S. Serial No. 10/001,486
Filed: November 15, 2001
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REMARKS

Claims 16-18 are pending and being examined. Applicants have amended claim 16. Entry of these amendments is respectfully requested.

Support for amended claim 16 may be found in originally filed specification at page 7, line 21; page 8, line 3, line 6, and line 15; page 28, line 28; page 29, line 5 and lines 15-16 and page 59, lines 3-7.

Applicants have amended claim 16 herein. The changes in claim 16 do not involve new matter, and are supported by the specification as originally filed. Entry of these amendments is respectfully requested.

TITLE AND SPECIFICATION

In paragraph 3, the Examiner objected to the specification. Allegedly, the cited documents are not considered to have been properly incorporated by reference and as such have not been considered with any effect towards their fulfilling, in the whole or part, the enablement, written description, or best mode requirements of 35 U.S.C. §112.

In response, Applicants point out that the claimed methods are enabled as disclosed by the actual data provided in the specification as originally filed. As such, the objection is moot. The cited references are merely included in the specification to show, e.g., the state of the art in accord with MPEP §2163.07(b). Instead of repeating some information contained in another document, Applicants have incorporated by reference the information into the application.

In paragraph 4, Applicants herein amend the title of the application to reflect the invention to which the claims are directed as required by the Office.

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REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH:

In paragraphs 5-9, the Patent Office rejected claims 16-18 under 35 U.S.C. §112, first paragraph because these claims contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention

Applicants respectfully disagree.

The specification as originally filed discloses actual enabling experiments embodying the claimed methods. Further, Applicants have disclosed the requisite starting materials needed to practice the full scope of the invention.

For example, Applicants disclosed actual examples regarding how to make cells having tandem arrays (specification at page 58-63) and has deposited an example of such a cell (ATCC accession number CRL-11998). Furthermore, Applicants teach alternatives ways for making arrays in the specification at page 57, lines 20-30; page 58, lines 1-3; page 59, lines 18-21; page 60, line 26-27; and page 61, lines 1-21.

Further, the specification provides adequate written description of examples of steroid response elements in an array where the steroid nuclear receptor is ER, AR, GR, PR, and MR (specification at page 13, lines 20-25; page 17, lines 8-23; page 18, lines 4-7; page 50, lines 25-31; and page 51, lines 1-2 and lines 7-16). With regard to ER, Applicants teach the sequence of the steroid response element in the specification at page 59, lines 4-5 and methods for making it in the specification at page 59, lines 5-9 and lines 14-23. With regard to GR, Applicants teach the sequence of the steroid response element at page 59, lines 3-4 and lines 10-14. With regard to AR, PR, and MR, the consensus sequence

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of each of these steroid response elements are the same, and each receptor can bind to the steroid hormone-responsive elements that is recognized by GR.

Additionally, Applicants have actually demonstrated translocation of the steroid receptor to the nucleus of a mammalian cell (specification at page 47, lines 1-24 and 26-31, and page 48, lines 1-8) as part of a screening assay to find ligands that activates the translocation of a steroid receptor to the nucleus in a mammalian cell. In one embodiment, the ligand is dexamethasone and a dose response curve for dexamethasone is provided (specification at page 47, lines 1-8). In another embodiment, the ligand is RU486 (specification at page 47, line 27; and page 48, lines 1-4). In yet another embodiment, the ligand is progesterone (specification at page 48, lines 5-7). When a non-ligand for a particular receptor is used to treat a fluorescent receptor, no translocation is observed, demonstrating importance of activating the steroid receptor for translocation to occur from cytoplasm to the nucleus (specification at page 48, lines 7-8).

Further, the claims fully enable the use of any mammalian nucleated cell in the claimed methods because the steroid hormone signal transduction pathway is conserved in all eukaryotic cells, including mammalian cells, and translocation or movement of a steroid receptor from the cytoplasm to the cell nucleus is a necessary step for steroid receptors to modulate steroid hormone-responsive gene expression by steroid hormones.

Additionally, the Examiner objected to the claims which encompass any and all possible combinations of said steroid response elements. In response, Applicants have amended the claims to recite "a plurality of steroid receptor response elements, wherein the steroid receptor response elements is AGAACCA (SEQ ID NO:4) or AGGTCA (SEQ ID NO:5)." Therefore, although fully enabled, in order to further the prosecution of the subject application, the claims now require that the steroid receptor response elements be either AGAACCA (SEQ ID NO:4) or AGGTCA (SEQ ID NO:5).

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In paragraphs 10-11, the Patent Office also rejected claims 16-18 under 35 U.S.C. §112, first paragraph because these claims contain subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants respectfully disagree for the reasons disclosed above. Applicants have described actual assays confirming the claimed methods and discovered actual ligands that fall under the claimed methods. Accordingly, Applicants are in possession of the claimed invention as originally filed.

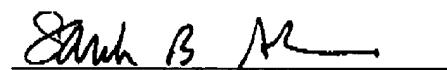
CONCLUSION

Applicants believe that all grounds for rejection of the claims have been successfully overcome and that the claims are now in condition for allowance. Withdrawal of the Examiner's remaining rejections is requested and prompt allowance of the claims is solicited. If any issues remain in connection with the claims, the Examiner is encouraged to contact the undersigned by telephone to discuss the same.

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No fee, other than the \$510.00 three-month extension fee, is deemed necessary in connection with the filing of this response. If any further fee is necessary, the Patent Office is authorized to charge any additional fee to Deposit Account No. 50-0306.

Respectfully submitted,



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